



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**Note to Reader**  
**January 15, 1998**

**Background:** As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

**Note:** This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket ( RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', is written over the typed name and title.

Jack E. Housenger, Acting Director  
Special Review and Reregistration Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

January 12, 1999

MEMORANDUM

SUBJECT: PROPETAMPHOS. Draft Product and Residue Chemistry  
Chapters of RED. Chemical Number 113601. DP Barcode  
D252129.

FROM: Steven A. Knizner, Branch Senior Scientist  
Risk Characterization and Analysis Branch  
Health Effects Division (7509C)

TO: Christina Scheltema  
Special Review and Reregistration Division (7508C)

Attached please find the draft products and residue chemistry chapters for propetamphos. These chapters are currently undergoing secondary review in HED, but the conclusions concerning tolerance reassessment have already been determined to be correct.

**PROPETAMPHOS**  
**Shaughnessy No. 113601; Case 2550**  
**(DP Barcode 252129)**

**July 24, 1997**

**Contract No. 68-D4-0010**

**Submitted to:**  
**U.S. Environmental Protection Agency**  
**Arlington, VA**

**Submitted by:**  
**Dynamac Corporation**  
**1910 Sedwick Road**  
**Building 100, Suite B**  
**Durham, NC 27713**

# PROPETAMPHOS

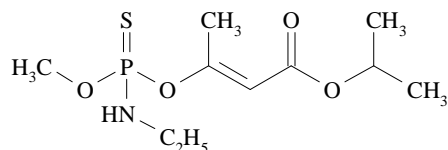
## REREGISTRATION ELIGIBILITY DECISION:

### DRAFT PRODUCT CHEMISTRY CONSIDERATIONS

Shaughnessy No. 113601; Case No. 2550

#### DESCRIPTION OF CHEMICAL

Propetamphos [(E)-1-methylethyl-3-[[[(ethylamino)methoxyphosphinothioyl]oxy]-2-butenate] is an insecticide registered for use in food handling establishments and storage/warehouse facilities.



Empirical Formula:	C <sub>10</sub> H <sub>20</sub> NO <sub>4</sub> PS
Molecular Weight:	281.31
CAS Registry No.:	31218-83-4
Shaughnessy No.:	113601

#### IDENTIFICATION OF ACTIVE INGREDIENT

Propetamphos is a yellowish oily liquid with a boiling point of 87-89 C. Propetamphos is practically insoluble in water (110 mg/L at 20 C), but is completely miscible in most organic solvents including acetone, chloroform, diethyl ether, ethanol, hexane, and xylene.

#### MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 5/29/97 identified a single propetamphos manufacturing-use product (MP) registered under Shaughnessy No. 113601: the Sandoz Agro, Inc. 90.7% T (EPA Reg. No. 2724-313). Because propetamphos is a List B chemical, only the 90.7% T/TGAI is subject to a reregistration eligibility decision.

#### REGULATORY BACKGROUND

The Propetamphos Phase 4 Review dated 11/30/90 by S. Funk determined that the available data concerning physical/chemical properties were acceptable for Phase 5 review, except for data pertaining to GLNs 63-10, 63-11, and 63-13 (OPPTS 830.7370, 830.7550-70, and 830.6313); additional data were required for the remaining product chemistry guidelines for the Sandoz propetamphos T/TGAI.

The current status of the product chemistry data requirements for the propetamphos technical product is presented in the attached data summary table. Refer to this table for a listing of the outstanding product chemistry data requirements.

## CONCLUSIONS

All pertinent data requirements are satisfied for the propetamphos 90.7% T/TGAI except for a new data requirement concerning UV/visible absorption for the PAI (OPPTS 830.7050). Provided that the registrant submits the data required in the attached data summary table for the 90.7% T/TGAI, and either certifies that the suppliers of beginning materials and the manufacturing process for the propetamphos TGAI have not changed since the last comprehensive product chemistry review or submits a complete updated product chemistry data package, CBRS has no objections to the reregistration of propetamphos with respect to product chemistry data requirements.

## AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s): 10213  
DP Barcode(s): D180678  
Subject: Propetamphos. Waiver for Dissociation Constant Study and Octanol/Water Partition Coefficient Study. Reregistration Case #2520.  
From: S. Knizner  
To: R. Whifers  
Dated: 8/14/92  
MRID(s): 41607407 and 41607410

CBRS No(s): 10218  
DP Barcode(s): D180675  
Subject: Propetamphos (113601) Reregistration. Product Chemistry Guideline 63-13 Stability.  
From: A. Aikens  
To: L. Deluise/R. Whifers  
Dated: 9/2/92  
MRID(s): 42254701

CBRS No(s): 10419  
DP Barcode(s): D181763  
Subject: Propetamphos: Zoecon Corp. Response to the Phase 4 Review dated 11/30/90: Product Chemistry Guidelines 61-1, 61-2, 61-3, 62-1, 62-2, 62-3. (Chemical No. 113601).  
From: A. Aikens  
To: L. Deluise/R. Whitters  
Dated: 2/12/93  
MRID(s): 42355801-42355804

CBRS No(s): TBA  
DP Barcode(s): TBA  
Subject:  
From: S. Funk  
To:  
Dated: Under review  
MRID(s): 41607408, 41607411, and 41607416

#### PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

#### References (cited):

41607407 Kazee, B. (1990) N-octanol/water Partition Coefficient of Propetamphos: Lab Project Number: 1456. Unpublished study prepared by Battelle. 14 p.

41607408 Kazee, B. (1990) Solubility of Propetamphos: Lab Project Number: 1457. Unpublished study prepared by Battelle. 13 p.

41607410 Kazee, B. (1990) Dissociation Constant of Propetamphos: Final Report: Lab Project Number: SC900059: 1454. Unpublished study prepared by Battelle. 10 p.

41607411 Schweitzer, M. (1990) Physical Characterization of Propetamphos: Final Report: Lab Project Number: SC900060; 1455. Unpublished study prepared by Battelle. 12 p.

41607416 Dublaski, A. (1990) Determination of the Vapor Pressure of Propetamphos: Lab Project Number: BE-P-106-90-A04-01; 1458. Unpublished study prepared by Battelle-Institut E. V. 17 p.

42254701 Clark, A. (1992) Stability for Propetamphos: Lab Project Number: 6449-F: 1715. Unpublished study prepared by Midwest Research Institute. 24 p.

42355801 Burleson, J.; Inada, S. (1992) Propetamphos: Manufacturing Procedure and Beginning Materials: Lab Project Number: 9005 SAN 139191 TC. Unpublished study prepared by Nippon Kayaku Co. Ltd. and Zoecon Corp. 91 p.

42355802 Reuter, K.; Burleson, J.; Kayaku, N. (1992) Discussion of Impurities of Propetamphos Technical: Lab Project Number: REF 4500/KRE/RC: 9005 SAN 139191 TC. Unpublished study prepared by Sandoz Ltd., Nippon Kayaku Co. Ltd. and Zoecon Corp. 23 p.

42355803 Ko, J.; Nguyen, J.; Lewis, S.; et al. (1992) Analysis and Certification of Ingredients and Impurities in Five Separate Batches of Propetamphos Technical Material: Lab Project Number: 1864. Unpublished study prepared by Zoecon Corp. 72 p.

42355804 Ko, J.; Nyuyen, J.; Lewis, S.; et al. (1992) Precision and Accuracy for Current Analytical Procedures, CAP 315, CAP 341, CAP 342, and CAP 344, Used to Analyze Components of Propetamphos Technical Material: Lab Project Number: 1863: 9005 SAN 139 I 91 TC. Unpublished study prepared by Zoecon Corp. 64 p.



Case No. 2550  
Chemical No. 113601

Case Name: Propetamphos  
Registrant: Sandoz Agro, Inc.  
Product(s): 90.7% T (EPA Reg. No. 2724-313)

#### PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? <sup>1</sup>	MRID Number <sup>2</sup>
830.1550	Product Identity and Disclosure of Ingredients	Y <sup>3</sup>	42355802, CSF 6/3/92
830.1600	Starting Materials and Manufacturing Process	Y	42355801
830.1620			
830.1650			
830.1670	Discussion of Formation of Impurities	Y	42355802
830.1700	Preliminary Analysis	Y	42355803
830.1750	Certification of Ingredient Limits	Y	42355802, CSF 6/3/92
830.1800	Analytical Methods to Verify the Certified Limits	Y	42355803, 42355804
830.6302	Color	Y	41607411 <sup>4</sup>
830.6303	Physical State	Y	41607411 <sup>4</sup>
830.6304	Odor	Y	41607411 <sup>4</sup>
830.6313	Stability	Y	42254701 <sup>5</sup>
830.7000	pH	N/A <sup>6</sup>	
830.7050	UV/Visible Absorption	N <sup>7</sup>	
830.7200	Melting Point/Melting Range	N/A <sup>8</sup>	
830.7220	Boiling Point/Boiling Range	Y	41607411 <sup>4</sup>
830.7300	Density/Relative Density/Bulk Density	Y	41607411 <sup>4</sup>
830.7370	Dissociation Constant in Water	Y	41607410 <sup>9</sup>
830.7550	Partition Coefficient (Octanol/Water)	Y	41607407 <sup>9</sup>
830.7560			
830.7570			
830.7840	Solubility	Y	41607408 <sup>4</sup>
830.7860			
830.7950	Vapor Pressure	Y	41607416 <sup>4</sup>

<sup>1</sup> Y = Yes; N = No; N/A = Not Applicable.

<sup>2</sup> References were reviewed under CBRS No. 10419, D181763, 2/12/93, A. Aikens unless otherwise noted.

<sup>3</sup> We note that the label claim of 90.7% is not in agreement with the nominal concentration of the active ingredient in the product as required under PR notice 91-2 dated 5/2/91.

<sup>4</sup> CBRS No. TBA, DP Barcode TBA, currently under review.

<sup>5</sup> CBRS No. 10218, D180675, 9/2/92, A. Aikens.

<sup>6</sup> Data are not required because the T/TGAI is not dispersible in water.

<sup>7</sup> The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

<sup>8</sup> Data are not required because the T/TGAI is a liquid at room temperature.

<sup>9</sup> CBRS No. 10213, D180678, 8/14/92, S. Knizner.

# PROPETAMPHOS

## REREGISTRATION ELIGIBILITY DECISION

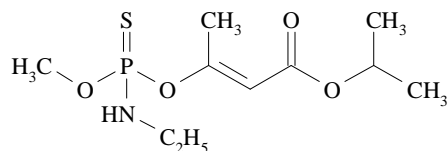
### DRAFT RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 113601; Case 2550

(DP Barcode 252129)

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# PROPETAMPHOS



## REREGISTRATION ELIGIBILITY DOCUMENT

### RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 113601; Case 2550

### INTRODUCTION

Propetamphos [1-methylethyl (E)-3-(((ethylamino)methoxyphosphinothioyl)oxy)-2-butenate] is an insecticide registered for use in food handling establishments and storage facilities.

Propetamphos is manufactured by Sandoz Agro, Inc., the basic producer, under the trade names Safrothin® and Zoecon®. Propetamphos formulations registered for use in food handling establishments and storage facilities include emulsifiable concentrate (EC), soluble concentrate (SC/L), and pressurized liquid (PrL) formulations. These formulations may be applied as spot and crack or crevice treatments to food handling areas or food handling establishments and in food store facilities.

### REGULATORY BACKGROUND

Propetamphos is a list B reregistration chemical and was the subject of a Phase 4 Review dated 11/30/90 (S. Funk) that summarized regulatory conclusions on the available residue chemistry data and specified that additional data were required for reregistration purposes. Numerous submissions of data have been received since the Phase 4 Review was issued. The information contained in this document outlines the current Residue Chemistry Science Assessments with respect to the reregistration of propetamphos.

Tolerances for propetamphos residues in/on processed food and animal feed commodities are currently expressed in terms of propetamphos, 1-methylethyl (E)-3-(((ethylamino)methoxyphosphinothioyl)oxy)-2-butenate, [40 CFR §185.5100 and §186.5100]. Adequate methods are available for the enforcement of established tolerances, as currently defined. Based upon the available food degradation study, the Agency (CBRS No. 16992, DP Barcode D223757, S. Funk, 9/17/96) has concluded that the residues to be regulated in food commodities will consist of propetamphos *per se*.

## SUMMARY OF SCIENCE FINDINGS

### OPPTS GLN 860.1200: Directions for Use

A search of the Agency's Reference Files System (REFS) on 7/8/97 indicates that there are four propetamphos end-use products (EPs) with uses for food handling establishments registered to Sandoz Agro, Inc. These EPs are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
2724-314	1/97	4.3 lb/gal EC	Safrothin® Emulsifiable Concentrate Insecticide
2724-340	2/96	1.0% PrL	Zoecon® RF-256 Aerosol
2724-449	4/97	4.1 lb/gal EC	Zoecon® 8718 EW
2724-450	10/94	1.7 lb/gal SC/L	Zoecon® 9001 EW

These formulations are registered for applications of a 0.5-1.0% ai solution as spot and crack or crevice treatments in food handling areas of food handling establishments. For applications in food handling areas, the EC and SC/L formulations may only be diluted with water. Repeated applications are allowed with no more than one application every 7 days, and no more than two applications in a 30-day period.

All four labels also allow applications of a 1.0% ai solution to pantry shelves and cupboards from which utensils, foodstuffs, and shelf paper have been removed. Prior to replacement of food stuffs and utensils, the spray should be allowed to dry and fresh shelf paper should be applied.

A tabular summary of the residue chemistry science assessments for reregistration of propetamphos is presented in Table A. The conclusions listed in Table A regarding the reregistration eligibility of propetamphos food uses are based on the use patterns registered by the basic producer, Sandoz Agro, Inc. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producers labels.

#### OPPTS GLN 860.1300: Nature of the Residue in Food

The qualitative nature of the residue in food commodities is adequately understood based upon metabolism studies examining the degradation of [ $^{14}\text{C}$ ]propetamphos in tomato juice, butter, bread, and hamburger meat. Propetamphos did not degrade in exposed foodstuffs held at room temperature for intervals (6-48 hours) typical of those encountered during the treatment of

restaurants and similar establishments. Greater than 98% of the total radioactive residue was identified as [<sup>14</sup>C]propetamphos. The residue to regulated in food is propetamphos *per se*.

#### OPPTS GLN 860.1300: Nature of the Residue in Plants

Plant metabolism studies are not required as propetamphos is not registered for use on food/feed crops.

#### OPPTS GLN 860.1300: Nature of the Residue in Livestock

As propetamphos is not registered for use on food/feed crops and label directions preclude the exposure of livestock and livestock feed items, the Agency has waived (CBRS No. 15392, 4/26/95) the requirement for livestock metabolism studies.

#### OPPTS GLN 860.1340: Residue Analytical Methods

Adequate analytical methodology is available for enforcing tolerances and collecting data on propetamphos residues in food commodities. A GC/flame photometric detection (FPD) enforcement method for determining propetamphos in fruit, meats, milk, and vegetables is listed in the Pesticide Analytical Manual (PAM), Vol. II, as Method I. This method involves extraction with acetone and clean up using an Extrelut column, hexane/acetonitrile partitioning, and silica gel column chromatography prior to analysis by GC/FPD in the phosphorus mode. The limit of detection is 0.01 ppm.

In addition, the registrant has proposed a GC/mass spectrometry detection (MSD) method for enforcing tolerances for propetamphos residues in/on food commodities. The proposed GC/MSD enforcement method is a modification of Method I. Residues of propetamphos are extracted from solid matrices with acetonitrile or acetone (butter and foods with high sugar content), filtered, and dried over anhydrous sodium sulfate. For liquid matrices, samples are cleaned up on an Extrelut column eluted with hexane. Purified residues are determined by GC/MSD. The validated limit of quantitation is 0.1 ppm. This method has undergone a successful method validation trial by the Agency (DP Barcode D225836, S. Funk, 5/14/96), and the registrant has submitted a revised version of the method that includes corrections requested by the Agency (DP Barcode D231395, S. Funk, 3/18/97).

Residue data on propetamphos in/on food commodities from the residue study for food handling establishments were been collected using the proposed GC/MSD enforcement method.

#### OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database indicates that propetamphos is completely recovered using FDA Multiresidue Protocols D and E (PAM I Sections 232.4 and 211.1).

#### OPPTS GLN 860.1380: Storage Stability Data

Requirements for storage stability data are satisfied for purposes of reregistration. Acceptable storage stability data are available to support the magnitude of the residue in foods study. When corrected for concurrent method recoveries, the recovery of propetamphos was 77-113% from samples of apples, beer, bologna, bread, butter, flour, hamburger, lettuce, milk, Rice Krispies®, and sugar fortified with propetamphos at 0.1 ppm and stored at -15 C for as long as 66 days prior to extraction. Only recoveries from fortified macaroni stored frozen for 29-50 days were unacceptable (58-66%).

#### OPPTS GLN 860.1500: Magnitude of the Residue in Crop Plants

Propetamphos is presently not registered for use on food and/or feed crops; therefore, no residue chemistry data are required under this guideline topic.

#### OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

Propetamphos is presently not registered for use on food and/or feed crops; therefore, no residue chemistry data are required under this guideline topic.

#### OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Propetamphos is presently not registered for use on livestock or feed crops; therefore, no residue chemistry data are required under this guideline topic.

#### OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, and Irrigated Crops

Propetamphos is presently not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

#### OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments

Reregistration requirements for magnitude of the residue in food-handling establishments are fulfilled. Adequate data are available depicting residues of propetamphos in representative food



commodities (apples, beer, bologna, bread, butter, flour, hamburger, lettuce, macaroni, milk, Rice Krispies®, and sugar) exposed, in open and closed containers on tables, to propetamphos treatments reflecting the registered use pattern for food handling areas. Two and 8 hours following a single application of both spot and crack/crevice treatments of 1% propetamphos, residues of propetamphos were <0.01 ppm in all food samples held in closed containers. Residues of propetamphos were ≤0.022 ppm in uncovered samples of apples, beer, flour, hamburger, lettuce, macaroni, milk, Rice Krispies®, and sugar. The maximum residues of propetamphos were found in uncovered samples of bread (0.038-0.078 ppm) and butter (0.015-0.024 ppm).

In addition, the registrant provided the Agency with a dislodgeability study indicating that propetamphos is not readily dislodged from smooth vinyl surfaces and that the percent removable decreases rapidly with time, with <10% of the residue removable after 4 days. Given the label-specified 7-day reapplication interval and limit of two applications per 30 day period, combined with low dislodgeability, the Agency has concluded that the potential for transfer of significant quantities of propetamphos from surfaces, such as pantry shelves, to food is unlikely.

#### OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

Propetamphos is presently not registered for use on food and/or feed crops; therefore, no residue chemistry data are required under this guideline topic.

#### OPPTS GLN 860.1900: Field Accumulation in Rotational Crops

Propetamphos is presently not registered for use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

Table A. Residue Chemistry Science Assessments for Reregistration of Propetamphos.

OPPTS GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
860.1200: Directions for Use	N/A	No	
860.1300: Nature of the Residue			
- Food	N/A	No	43890201 <sup>2</sup>
860.1340: Residue Analytical Methods	N/A	No	41997101 <sup>3</sup> 41997102 <sup>3</sup> 41997103 <sup>3</sup> 43193301 <sup>4</sup> 43193302 <sup>4</sup> 43193303 <sup>4</sup> 44150501 <sup>5</sup>
860.1360: Multiresidue Method	N/A	No	
860.1380: Storage Stability	N/A	No	41997103 <sup>3</sup> 43193303 <sup>4</sup>
860.1500: Magnitude of the Residue in Crop Plants	N/A	No	
860.1520: Magnitude of the Residues in Processed Food/Feed			
- Animal Feed	0.1 [§186.5100]	No	
860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs	N/A	No	
860.1400: Magnitude of the Residue in water, fish, and irrigated crops	N/A	No	
860.1460: Magnitude of the Residue in Food Handling Establishments			
- Processed Food	0.1 [§185.5100]	No	41581201 <sup>6</sup> 41997103 <sup>3</sup>
860.1850: Confined Accumulation in Rotational Crops	N/A	No	
860.1900: Field Accumulation in Rotational Crops	N/A	N/A	

1. References were reviewed as cited.
2. CBRS No. 16992, DP Barcode D223757, S. Funk, 9/17/96.
3. CBRS No. 8589, DP Barcode D168666, S. Funk, 12/4/92.
4. CBRS No. 13843, DP Barcode D204202, S. Funk, 9/22/94.
5. CBRS No. 17654, DP Barcode D231395, S. Funk, 3/18/97.
6. CBRS. No. 13878, DP Barcode D204297, S. Funk, 7/19/94.

## TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of propetamphos in food commodities and animal feeds resulting from the application of propetamphos to food/feed handling establishments are currently expressed in terms of propetamphos *per se* [40 CFR §185.5100 and §186.5100]. The Agency (S. Funk, 9/17/96) has concluded that the residues to be regulated in food commodities for will consist of propetamphos *per se*.

### Tolerance Listed Under 40 CFR §185.5100:

Reregistration requirements for data depicting residues of propetamphos in/on food commodities following applications representative of the use in food handling establishments are fulfilled, and sufficient data are available to ascertain the adequacy of the established tolerance for residues in/on food commodities. The available data indicate that the current 0.1 ppm tolerance for residues of propetamphos in food commodities is appropriate.

### Tolerance Listed Under 40 CFR §186.5100:

The tolerance for propetamphos residues in animal feeds should be revoked as uses allowing the application of propetamphos to animal feed handling and storage facilities have been removed from all product labels.

## DIETARY EXPOSURE ASSESSMENT SUMMARY

An adequate food degradation study and adequate residue data for food commodities are available for reregistration and risk assessment purposes. A reliable risk assessment for the use of propetamphos in food handling establishments and food storage facilities can be conducted at this time using the current 0.1 ppm tolerance for processed foods.

## CODEX HARMONIZATION

As there are no established or proposed Codex MRLs for propetamphos residues, no compatibility questions exist with respect to U.S. tolerances and Codex.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No: 8589  
DP Barcode: D168666  
Subject: Reregistration of Propetamphos: Analytical Method, Food/Feed Handling, and Product Chemistry.  
From: S. Funk  
To: J. Ellenberger/R. Whitters  
Dated: 12/4/92  
MRID(s) 41997101, 41997102, and 41997103

CBRS No: 13878  
DP Barcode: D204297  
Subject: Propetamphos: Dislodgeability Study as Substitute for Additional Food/Feed Handling Use Study.  
From: S. Funk  
To: K. Davis/R. Whitters  
Dated: 7/19/94  
MRID(s) 41581201

CBRS No: 13843  
DP Barcode: D204202  
Subject: Propetamphos: Analytical Method (171-4(c)); Magnitude of the Residue in Food/Feed Handling Establishments (171-4(i)).  
From: S. Funk  
To: K. Davis/R. Whitters  
Dated: 9/22/94  
MRID(s) 43193301, 43193302, and 43193303

CBRS No: 15392  
DP Barcode: D213823  
Subject: Label Amendments and Request for Waiver from GLN 171-4(b).  
From: S. Funk  
To: K. Davis  
Dated: 4/26/95  
MRID(s) None

CBRS No: 17185  
DP Barcode: D225836  
Subject: Propetamphos: EPA Method Validation.  
From: S. Funk  
To: P. Deschamp  
Dated: 5/14/96  
MRID(s) None

CBRS No: 16992  
DP Barcode: D223757  
Subject: Propetamphos: Sandoz Agro Inc. Food Degradation Study.  
From: S. Funk  
To: P. Deschamp  
Dated: 9/17/96  
MRID(s) 43890201

CBRS No: 17654  
DP Barcode: D231395  
Subject: Propetamphos: Enforcement Method Corrections.  
From: S. Funk  
To: P. Deschamp  
Dated: 3/18/97  
MRID(s) 44150501

#### RESIDUE CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

41581201 Huang, F. (1988) Propetamphos Dislodgeability Study Report: Lab Project Number: 88-820-0400. Unpublished study prepared by Mid-west Regional Chemistry Laboratory/Environmental Science & Engineering, Inc. 71 p.

41997101 Schweitzer, M.; Summer, S. (1991) Method Development and Validation of Propetamphos Residue Analysis in Food Commodities: Final Report. Lab Project Number: SC900078. Battelle. 154 p.

41997102 Neslund, C. (1991) Confirmation of the Tolerance Enforcement Method for Propetamphos Residue on Food Commodities: Final Report: Lab Project Number: 2985: 1618. Unpublished study prepared by Lancaster Labs., Inc. 178 p.

41997103 Rudolph, R. (1991) Propetamphos Residue in Representative Food Commodities Resulting from Exposure to Safroin 1% Aerosol: Lab Project Number: 1452: R256SAN139I1AE-RES. Unpublished study prepared by Battelle. 137 p.

43193301 Lephart, J. (1994) Response to United States Environmental Protection Agency Letter, October 28, 1993, Regarding Propetamphos Residue Studies (Part 1: Method Development): Supplement: Lab Project Number: 1538. Unpublished study prepared by Sandoz Agro, Inc. 13 p.

43193302 Lephart, J. (1994) Response to United States Environmental Protection Agency Letter, October 28, 1993, Regarding Propetamphos Residue Studies (Part 2: Method Confirmation): Supplement: Lab Project Number: 1618. Unpublished study prepared by Sandoz Agro, Inc. 13 p.

43193303 Lephart, J. (1994) Response to United States Environmental Protection Agency Letter, October 28, 1993, Regarding Propetamphos Residue Studies (Part 3: Residue Quantitation): Supplement: Lab Project Number: 1452. Unpublished study prepared by Sandoz Agro, Inc. 13 p.

43890201 Cannon, J. (1995) Evaluation of Propetamphos Degradation in Four Food Matrices: Lab Project Number: 3861: 0924-167: 2207. Unpublished study prepared by Midwest Research Institute. 71 p.

44150501 Andrews, K. (1996) Method Development and Validation of Propetamphos Residue Analysis in Food Commodities: Lab Project Number: SC900078: 1538. Unpublished study prepared by Battelle. 9 p.